

In the Supreme Court of the United States

OCTOBER TERM, 1966

Nos. 336, 438

**THE TOILET GOODS ASSOCIATION, INC., ET AL.,
PETITIONERS**

v.

**JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION,
AND WELFARE, AND JAMES L. GODDARD, COMMIS-
SIONER OF FOOD AND DRUGS**

**JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION,
AND WELFARE, AND JAMES L. GODDARD, COMMIS-
SIONER OF FOOD AND DRUGS, PETITIONERS**

v.

THE TOILET GOODS ASSOCIATION, INC., ET AL.

**ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF
APPEALS FOR THE SECOND CIRCUIT**

**REPLY BRIEF FOR RESPONDENTS IN NO. 336 AND FOR
PETITIONERS IN NO. 438**

1. We observed in our main brief (pp. 9-12) that the sole issue on the first three counts of the complaint in this case is whether the statute authorizes

the Food and Drug Administration to require pre-marketing clearance in the form of listing and certification of finished cosmetic products, diluents and certain kinds of hair dyes. We attempted there to distinguish that question from a challenge to the power of the Food and Drug Administration to examine such products as part of an inquiry to determine whether color ingredients contained therein are "safe-for-use."

Although respondents' brief does not squarely take issue with these observations,¹ it occasionally suggests that in enacting the Color Additive Amendments of 1960 Congress did not intend to authorize "pretesting" of finished cosmetic products.² This suggestion is so plainly contrary to the purpose of the 1960 amendments that it cannot go unchallenged.

The 1960 amendments were suggested by the Food and Drug Administration which had been authorized, by this Court's construction of the previous statutory language in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, to bar the use in foods, drugs and cosmetics of any color additive which was not absolutely harmless. In enacting the 1960 amendments, Congress conferred on those responsible for administration of the Act the duty of assuring "the safety of the use or uses

¹ In discussing the "burdens imposed on the cosmetic industry by the regulations" (Resp. Br. 23-25), it enumerates only such "burdens" as are attributable to separate listing and certification. And respondents' discussion of the allegedly "immediate impact" of the regulations also focuses on the effects of a requirement that petitions for listing finished cosmetic products be filed forthwith (Resp. Br. 46-49).

² See Resp. Br. 11, 13, 24, 48.

for which a particular color additive is listed" by prescribing "the conditions under which such additive may be safely employed for such use or uses", including not only specifications regarding maximum quantities but also specifications "as to the manner in which such additive may be added to used in or on" any food, drug or cosmetic. Section 706(b)(3), 21 U.S.C. 376(b)(3).

Nothing could be clearer than that Congress did not intend the Commissioner of Food and Drugs to be limited in his examination to the dye or pigment itself, separate and apart from the food, drug or cosmetic in which it is used. The plain purpose of the law would be defeated by an application of the 1960 Act which so limited the concern of the Food and Drug Administration. Its consequence would be a focussing of attention on the color component itself—separate and apart from its ultimate use in a cosmetic—and this would disable the Commissioner from determining and prescribing the restrictions necessary to insure the "safety in use" of the pigment or dye. Color components are rarely used separately, and the goal of consumer safety could plainly not be realized if only the component were subjected to testing and close scrutiny.

2. We submit, therefore, that "pretesting" of finished cosmetic products and diluents is an essential phase of the administration of the "safety-in-use" standard prescribed by the 1960 Act, irrespective of whether the finished cosmetics are themselves "color additives" so as to require their listing and certification. In determining whether to approve a pigment

or dye as safe for use in a finished cosmetic product, the Food and Drug Administration will ordinarily find it necessary to require the "pretesting" of the finished product and of the diluents it contains. Once the color ingredient is determined to be safe for use under these circumstances, that finding applies necessarily to the finished product as well as to its components. Whether the final product is or is not separately "listed" is, therefore, of no practical consequence, and the Commissioner does not read the statute as requiring separate "listing" of cosmetic formulae in these circumstances.

3. This demonstrates, we submit, how unreal this controversy is at the present time. If respondents submit petitions with adequate supporting material for listing of color ingredients for their specific intended use, and if the Commissioner determines that the particular uses are safe, the ingredients and the finished products will, in effect, be "listed" simultaneously. Nothing in the statute or regulations requires a separate formal paragraph in the Code of Federal Regulations for each "color additive," and listings may be sought and granted together for related products subject to the Act.^{*} Consequently, respondents cannot know today whether the Food and Drug Administration subjected them to any disadvantage whatever as a result of the challenged regulations.

^{*} Cellophane, for example, is a "food additive" when used in food packaging. The substances which may be used in cellophane are enumerated together (21 C.F.R. 121-2507), and there is no separate listing of each of the separate compositions.

4. Respondents' claim that an immediate staggering financial burden is imposed by the certification and listing requirement is totally unreal. Respondents are not obliged to submit 2700 formulae for separate "listing" (Resp. Br. 23-24). Formulae may be grouped according to their common base or common coloring ingredient, and a petition for listing may be submitted for the entire group—subject only to a \$250 fee for each added diluent. See 21 C.F.R. 8.50(j). The \$2600 payment required by 21 C.F.R. 8.50(c) is a deposit which is applied against the Food and Drug Administration's actual costs of processing the petition. If differing formulae requiring substantial additional verification are combined in a single petition the cost may exceed that figure and an added deposit will be requested. If the costs of processing are less than \$2600, the excess will be refunded. The extent of exaggeration in respondents' alleged costs becomes obvious if it is considered in light of the total budget of the Food and Drug Administration. In fiscal 1967, the complete budget was about \$65 million, with only \$1½ million being used for food and color additive preclearance. And it is entirely clear that the costs of chemical pretesting will not even remotely approach the figures cited by respondents (Resp. Br. 24) because that figure is arrived at by the mistaken procedure of multiplying the cost of testing a single cosmetic by the number of cosmetics produced (R. 101). Obviously the substantial similarity among lipstick ingredients, for example, rend-

ers it unnecessary to subject each of the different products to the same test of all components.

Respectfully submitted.

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JANUARY 1967.

